

Claims

1. A method for the concentration of PrP^{Sc} or
digestion products thereof, wherein a body fluid or flu-
5 idized organ is treated with solid phase material such as
e.g. magnetic beads (MB) whereby at least part of said
material or beads, respectively, carries a prion binding
site.
- 10 2. The method of claim 1, wherein the prion
binding site is a factor with prion binding activity
(PrPB).
- 15 3. The method of claim 1, wherein the fluid-
ized organ is homogenized tissue of central nervous sys-
tem.
4. The method of claim 1, wherein the fluid-
ized organ is homogenized brain tissue.
5. The method of claim 1, wherein the fluid
is a fluid that has been digested by proteinase K (PK).
- 20 6. The method of claim 2, wherein the solid
phase materials, e.g. MBs, carrying PrPB are prepared by
coupling MBs with blood serum, or blood plasma.
7. The method of claim 1, wherein the solid
phase materials, e.g. MBs, carrying PrPB are prepared by
coupling solid phase material with serum or plasma frac-
25 tion II of ammonium sulfate precipitation.
8. The method of claim 1, wherein the solid
phase materials, e.g. MBs, carrying PrPB are prepared by
coupling MBs with plasma fraction I of ammonium sulfate
precipitation.
- 30 9. The method of claim 1, wherein the solid
phase materials, e.g. MBs, carrying PrPB are prepared by
coupling solid phase material with PrPB_Ip or PrPB_{II}p or
PrPB_{II}s.
- 35 10. A method for the detection, and option-
ally quantification, of PrP^{Sc} or digestion products
thereof, wherein PrP^{Sc} is first concentrated according to

one of claims 1 to 6 and then detected, and optionally compared with a standard.

11. The method of claim 10, wherein the detection is performed by Western blot analysis.

5 12. PrPBIIIs which is a factor with prion binding activity in fraction II of ammonium sulfate precipitation of serum.

10 13. PrPBIIp which is a factor with prion binding activity in fraction II of ammonium sulfate precipitation of normal or fresh frozen plasma.

14. PrPBIp which is a factor with prion binding activity in fraction I of ammonium sulfate precipitation of plasma.

15 15. Solid phase material, such as MBs, carrying a PrPB.

16. A composition for the purification of body fluids and/or the sterilization of surgical or diagnostic tools comprising a PrPB, preferably coupled to a solid phase material.

20 17. A method for the sterilization of surgical or diagnostic tools wherein said tools are treated with a PrPB comprising composition, preferably a composition comprising PrPB coupled to a solid phase material.

25 18. A method for the concentration and/or isolation of PrPBs wherein serum or plasma is subjected to fractionated ammonium sulfate precipitation thus that at least one PrPB of interest is precipitated, preferably in only one fraction.

30 19. The method of claim 18, wherein the PrPB comprising fraction is further purified by further protein isolation methods.

35 20. A method for purification and/or removal of pathological prion protein from body fluids or fluidized organs, such as blood, urine, cerebrospinal fluid, brain tissue, lymph nodes, tonsils, or for the sterilization of surgical and/or diagnostic tools basing on the affinity of PrPB for the pathological prion protein.

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21. A method for the purification of body fluids, e.g. blood units, wherein the fluid is treated with PrPBIp.
 22. A therapy regimen based on the modulation 5 of production of PrPB for preventing the spread of prions in the body.
 23. The regimen of claim 19, wherein the PrPB is PrPBIp.
 24. A test for the detection of pathological 10 prion protein in body fluids or organs such as blood, urine, cerebrospinal fluid, brain tissue, lymph nodes, tonsils etc, that utilizes the specific binding properties of PrPB to pathological prion protein.
 25. The test of claim 24 that is embodied as 15 a microtiter plate format immunoassay, e.g. ELISA assay, an immunoprecipitation assay, a BIACORE assay, a immuno-cytochemical assay, a histoblot assay, etc.
 26. A DNA sequence specific for biosynthesis of PrPB and/or an expression vector comprising same.
 27. A method for purification of PrPB by using 20 Prp27-30 as bait.
 28. Monoclonal and polyclonal antibodies produced in animals, such as mice, rabbits, chicken, or other species, and directed against PrPB.
 29. Single-chain Fv fragments and other types 25 of fragments of antibodies produced in recombinant phages or in other recombinant systems, and directed against PrPB.
 30. A test predictive of susceptibility to 30 prion diseases based on polymorphisms of PrPB, or on variations in the strength and pattern of production of PrPB.
 31. A transgenic animal, in particular mouse 35 that overproduces PrPB in brain, lymph nodes, or other organs, to be used in a bioassay for prions.

32. A knockout animal, in particular a knock-out mouse, which is devoid of PrPB, to be used in a bio-assay for prions.

33. Production method of PrPB by expressing a DNA sequence specific for the biosynthesis of PrPB in a suitable host cell, such as bacteria, yeast, fungi, or eukaryotic cells, and by purification of PrPB from the aforementioned organisms.

34. Use of natural or synthetic PrPB as a medicament for therapeutical applications in humans and animals.

35. A vaccination of organisms with natural or synthetic PrPB, in particular PrPBIp.

36. A diagnostic assay for human and/or animal diseases resulting from abnormal production and/or metabolism of PrPB.